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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,168	09/25/2003	Gil M. Vardi	1001.2278101	2222

11050 7590 03/07/2011

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EXAMINER	
HOUSTON, ELIZABETH	
ART UNIT	PAPER NUMBER
3731	
MAIL DATE	DELIVERY MODE
03/07/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,168	VARDI ET AL.	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,8,28-30,32 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 5, 28-30, 32, 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. For the record, claims 4, 7, 17 and 22 claim subject matter that does not have support in the parent case (09/860,744), therefore they will not receive the benefit of the earlier filing date.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 4, 5, 8, 28-30, 32-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites the limitation "an intermediate region of at least 10 cm in length disposed between the proximal end region and the distal end region". There is no disclosure in the specification as to what constitutes the intermediate region or its length, thus there is no way for one of skill in the art to know what delineates the intermediate region or how to measure it.

4. Claim 28 recites “the bond is spaced form the balloon by around 10 cm or more, which has no upper limit. However, the specification (page 8) only provides support for a distance of 1–100cm. The same assessment applies to claims 38 and 40 as well.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 28 recites the limitation "the bond" twice in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 5 recites that the port is positioned between 10 and 50 centimeters from the distal end of the catheter. However Claim 1 recites that the intermediate portion (which does not include the distance of the proximal end portion or the distal end portion) is at least 10 cm. It is not clear how the distance from the port to the distal end of the catheter (which would include at least the distance of the branch guidewire enclosure) is 10 cm when only the intermediate portion of the guidewire enclosure is 10 cm.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 4, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith (US 6,273,879) in view of Adams (US 6,099,497) and further in view of Sirhan (US 5,743,875)

10. Keith discloses a catheter system comprising: a catheter including a proximal end and a distal end, the catheter comprising: a first tubular member/first catheter (for example 22 and 24; C5:L33-40), including a proximal end (for example near 28) and a distal end (34), the first tubular member defining an inflation lumen (62 and 104) of the catheter and extending distally from the proximal end of the catheter; a second tubular member/first distal tube (80) defining a main guidewire lumen (52), wherein the distal end (90) of the second tubular member is a distal end of the catheter and the proximal end of the second tubular member has a proximal end region (84) defining a proximal open end/main guidewire exit port (92), wherein the main guidewire lumen is configured to receive a main vessel guidewire therethrough (C7:L31-35), wherein the second tubular member is at least partially disposed within the inflation lumen of the first tubular member (Fig 2; C7:L12-21); a balloon (26) including a proximal waist (36) coupled to the first tubular member adjacent to the distal end of the first tubular member and a distal waist (40) coupled to the second tubular member adjacent to the distal end of the second tubular member (C8:L3-16). The proximal end of the first distal tube is disposed at or near the intermediate region of the first catheter tube (see for example Fig. 1, 2) and remains open to define a first guidewire exit port (92). The first distal tube is at least partially attached to the first catheter tub and at least partially disposed within the first catheter tube (see Fig. 1).

11. Keith does not disclose a branch guidewire enclosure or a stent. However, Adams discloses a balloon catheter that is designed to accommodate delivering a stent to an ostium or bifurcation. Adams incorporates a two guidewire system using two

separate guidewire lumens which is well known in the art for (see for example 136 in any of figs. 14a-18). In particular a branch guidewire enclosure/second distal tube (for example 166, 172 or 182) positioned alongside the first tubular member, wherein the branch guidewire enclosure defines a lumen (136) configured to receive a branch vessel guidewire therethrough (C10:L9-17), the branch guidewire enclosure including a proximal end region having a proximal end and a distal end region (see Fig. 17 and 18 and C10:L9-24), the proximal end of the branch guidewire enclosure defining a branch guidewire exit port (C10:L18-23 where the location of the port is considered to be the proximal end of the branch guidewire enclosure since the guidewire exits at the port and beyond the port, there would no longer be a guidewire enclosure), and a stent (For example Fig.7a, 64) having a lumen and a side opening (68) in a wall thereof, the stent positioned about at least a portion of the balloon, and wherein a distal portion of the branch guidewire enclosure is positioned through the lumen of the stent (C11:L24-30) and exits at the side opening; wherein the main guidewire exit port and the branch guidewire exit port are located proximal of the stent and distal of the proximal end of the catheter (C10:L18-23). The main guidewire exit port and the branch guidewire exit port are located substantially at the same longitudinal distance along the catheter (as understood by C10:L18-23). The second distal tube is detached from the first distal tube outside of the bond and the second distal tube does not include a balloon (see Fig. 18 and C12:L30-43).

12. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the balloon of Keith in order that it is capable of delivering a

stent. It is well known in the art to use catheters similarly structure to Keith for delivering stents and so it would be well within the skill of the ordinary artisan to use the balloon for stent delivery. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a branch guidewire enclosure to the balloon such that the device would be capable of delivering a stent to an ostium or bifurcation. Doing so would allow the user to precisely deliver a stent to an ostium or a bifurcation. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the guidewire structure such that it is bonded to the first tubular member of Keith since the first tubular member is the outermost surface of the catheter.

13. Modified Keith discloses that the branch guidewire enclosure has a proximal end region and a distal end region but does not explicitly disclose an intermediate region of at least 10 cm in length disposed between the proximal end region and the distal end region. However Adams does disclose that the length of the branch enclosure which typically defines the distal tip in the intermediate region of the balloon could be made longer such that its distal tip resides in the branch vessel (C12:L36-42). Further, Sirhan discloses a balloon catheter having a guidewire exit port located at between 5cm and 45 cm from the distal end of the catheter. Thus based on the teachings of Adams and Sirhan, it would have been well within the skill of the ordinary artisan to pursue known options within his or her technical grasp if it yields predictable results. In this case it would have been obvious to modify the distance of the guidewire port and thus the length of the intermediate portion of the branch guidewire portion in order to suit the particular intended use.

14. Modified Keith does not explicitly disclose that the branch guidewire enclosure is bonded only to the first tubular member and only bonded to the first tubular member at the proximal end region of the branch guidewire enclosure where the proximal end of the branch guidewire enclosure defines the exit port (i.e. the exit port is located at the bond). Adams shows in Fig. 17 and 18 that the guidewire enclosure is bonded to the tubular member at a distance from the proximal end of the balloon. Adams also explains that the exit port is located proximal of the balloon (C10:L18-24). Thus one of skill has three options available within his or her technical grasp: the exit port being distal of the bond, the exit port being at the same location of the bond and the exit port being proximal of the bond. Taking into consideration, these options in combination with the teachings of Adams of modifying the length of the guidewire branch enclosure and the teachings of Sirhan of modifying the location of the exit port, a person of ordinary skill would have good reason to pursue the known options within his or her technical grasp if it yields predictable results. It is well known in the art to modify dimension to suit the intended use of the device for example size of the patient or location of the body being treated.

15. Claim 28 requires that the bond (which is between the proximal end region of the second distal tube and the intermediate region of the first catheter tube) be located 10cm or more (and claims 38 and 40: 30 cm or more) from the balloon. Based on the teachings of modifying dimensions of the device as taught by Adams and Sirhan and discussed above. It would be well within the level of one of ordinary skill in the art at the time of the invention to modify the distance of the bond to meet the limitations of the

claim. Note that claims 28 and 38 do not limit the exit port (the proximal open end of the second distal tube) to be located at the bond region.

16. With respect to claim 4: Klein discloses a bonding material coupling the first tubular member and the second tubular member (C7:L22-30). It would have been obvious to one having ordinary skill in the art at the time of the invention to use a similar bonding material to couple the branch guidewire enclosure to device. Since the guidewire port would necessarily need to be bonded or coupled in some manner, it is common sense to do it in the same manner that other elements of the device are being coupled or bonded.

17. With respect to claim 30, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the length of the guidewire in light of the modifications with respect to location of the exit port. It is well known in the art to modify dimension to suit the intended use of the device for example size of the patient or location of the body being treated.

Response to Arguments

18. Applicant's arguments filed 06/30/10 have been considered but are moot in view of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth Houston/
Examiner, Art Unit 3731